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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,032	03/30/2000	Samir Kumar Brahmachari	KNS3.001AUS	7985

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/539,032	<b>Applicant(s)</b> BRAHMACHARI ET AL.	
	<b>Examiner</b> Marjorie A. Moran	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/05 has been entered. Claims 1-9 are pending.

***Claim and Specification Objections***

The objections to the specification and claims are hereby withdrawn in view of the amendment filed 12/23/05.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A step of "comparing extended conserved sequences ...to host organism protein sequences..." as newly recited in step (vi) of amended claim 1, is new matter. Original claim 1 recited comparison of genomes to identify sequences not commonly conserved between pathogenic versus non-pathogenic strains, and searching for given "conserved sequences" in a host genome and rejecting those not present in the host genome. The original claim steps are clearly directed to comparison of nucleic acid sequences (i.e. genomic material); the original claims did not recite comparison nor identification of any peptide sequences not present in a host genome. In the response filed 12/23/05, applicant points to pages 2 and 7 for support for the new step. Page 2 discloses that "invariant" proteins found in pathogens but not in a host indicate potential drug targets, thus providing support for "wherein ... conserved peptide sequences which are not present in host proteins are useful as drug targets" but does not provide support for an actual step of comparing peptides obtained by the claimed method steps to host protein sequences. The disclosure on page 2 for "genome-wide comparison" may refer to comparison of bacterial proteins in order to identify conserved sequences; it is not inherently a disclosure of comparing bacterial to host sequences. The steps disclosed on page 7 of the originally filed specification are identical to those of original claim 1 and are not supportive of the amended limitations as those set forth above for original claim 1. Example 7 on page 16 discloses that DNA gyrase is a KNOWN protein which is absent in humans, and that various invariant peptides from DNA gyrase COULD BE used as potential drug targets. It is noted that the peptides of Example 7 are selected from a protein previously known to be absent in humans. ANY peptide, conserved or

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not, from DNA gyrase, would be reasonably expected to be one "not present" in humans (i.e. a host organism). There is no disclosure anywhere in Example 7 for a step of "comparing " any conserved sequences/peptides to those of a host organism. The "identification" in Example 7 merely suggests that conserved peptides from a protein KNOWN to be absent in humans are possible binding sites/drug targets, but does not specifically compare peptides to those of a host organism. As neither the originally filed specification or claims provide support for new step (vii), applicant's arguments are not convincing and claim 1 is rejected for reciting new matter. Claims 2-9 depend from claim 1 and therefore also recite new matter.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the conserved peptide motifs" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, as parent claim 1 does not recite motifs anywhere. It is noted that claim 1 does recite "extended conserved peptide sequences" and "common peptide sequences" As it is unclear which, if either, of the phrases of claim 1 is intended as the antecedent basis for "the conserved peptide motifs" of claim 4, claim 4 is indefinite.

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Claims 5 and 6 recite the limitation "the ... conserved peptide sequences", each in line 2. There is insufficient antecedent basis for this limitation in the claims, as parent claim 1 recites both "**extended** conserved peptide sequences" and "common peptide sequences." As it is unclear which, if either, of the phrases of claim 1 is intended as the antecedent basis for "the ... conserved peptide sequences" of claims 5 and 6, the claims are indefinite.

Claim 5 recites increasing the number of conserved peptide sequences "by increasing the relatedness" among organisms. It is unclear what is meant by this phrase; i.e. reducing the number of organisms being compared such that those remaining are of "increased relatedness" compared to those removed; or considering only those with a specified (high) degree of relatedness; or actually mutating organisms such that they become more "related", or some other manipulation of organisms and/or data. As the step intended is unclear, the claim is indefinite. Applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Claim 6 recites a list of proteins wherein XVII is simply labeled "transporter". All of the other protein names are found in the NCBI database to be names for specific proteins or for a relatively small family of proteins with related function and/or sequence. There are over 200,000 "transporter" proteins in the NCBI database, with no discernable structural or sequence relationship. All "transport" something, but some are actually enzymes, some are "carrier" proteins, some are receptors, etc. As the metes and bounds intended by applicant for a "transporter" protein are unclear, claim 6 is indefinite.

Claim 8 recites the limitation "the organism" in the last line. There is insufficient antecedent basis for this limitation in the claim. Parent claim 1 recites "a host organism" in the preamble and "selected organisms" in steps (i) and (iii), therefore it is unclear what "organism" is intended as the antecedent basis for "the organism" of claim 8.

Claim 9 recites a step of iteratively comparing "data" on matched peptide locations. Parent claim 1 does not recite "peptide locations" nor "data" of any sort, therefore it is unclear what is to be iteratively compared in claim 9, and the claim is indefinite.

### ***Conclusion***

Claims 1-9 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
3/20/06